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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,158

04/12/2005

Hee-Sup Shin

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/531,158

**Applicant(s)**

SHIN ET AL.

**Examiner**

Olga N. Chernyshev

**Art Unit**

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-9 and 11 is/are pending in the application.  
4a) Of the above claim(s) 5-9 and 11 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1 and 4 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. Claims 1, 4-9 and 11 are pending in the instant application.

Claims 5-9 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 21, 2006.

Claims 1 and 4 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on July 30, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 4 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record in section 3 of Paper mailed on October 24, 2006, section 5 of Paper mailed on June 04, 2007 and section 6 of Paper mailed on January 31, 2008. The claim(s) contains subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At p. 4 of the Response, Applicant traverses the rejection by referring to the new set of data presented within the Declaration filed under Rule 132 by the inventors of the instant patent application. The experiments provide “data demonstrating that administration of  $\omega$ -conotoxin GVIA (an inhibitor of a  $\alpha 1B$  subunit of N-type calcium channel) can alleviate symptom of depression. The  $\omega$ -conotoxin GVIA compound was administered to wild-type mice and the effect on depression monitored using a forced swimming test”. Applicant further submits that “appropriate dosages can be determined empirically and the decision of effective dosage depends on the administration pathway, etc. and one skilled in the art can decide effective dosage”. Applicant’s arguments have been fully considered but not persuasive for the reasons included with the response to the Declaration of record.

The Declaration of Hee-Sup Shin and Chanki Kim under 37 CFR 1.132 filed July 30, 2008 is insufficient to overcome the rejection of claims 1 and 4 based upon lack of enablement under 35 USC 112, first paragraph as set forth in the last Office action for the following reasons.

The Declaration presents additional data obtained on wild-type mice injected intracerebrally with  $\omega$ -conotoxin GVIA (an inhibitor of an  $\alpha 1B$  subunit of N-type calcium channel) and subjected to behavioral tests (forced swimming tests). The data show that the drug-injected mice showed a significantly reduced immobility in the forced swimming test environment (pp. 2-3 and Figure of the Declaration). Applicants/declarants submit that “[a]s shown in the figure,  $\omega$ -conotoxin GVIA which is an inhibitor of  $\alpha 1B$  subunit of N-type calcium channel can alleviate symptom of depression when administered into a wild-type mice. Thus, a

skilled in the art can acknowledge that the present application complies with 35 USC 112, first paragraph from the above experimental data". The Examiner disagrees.

In order to satisfy the enablement requirement of section 112, an applicant must describe the manner of using the invention "in such full, clear, concise and exact terms as to enable any person skilled in the art ... to make and use the same..." 35 U.S.C §112, paragraph 1. Thus, the invention must be enabled at the time of filing and, therefore, the enablement cannot be supported by later obtained experimental results. *In re Rasmusson* Court held that

"If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis". *In re Rasmusson v. SmithKline Beecham Corp.* 75 USPQ2D 1297, p1301.

Further, the additional data on administration of one inhibitor of  $\alpha 1$  B subunit of N-type calcium channel injected intracerebrally, does not remedy the deficiency of the protocol for the claimed method, which, considered as a whole in light of the specification and given its broadest reasonable interpretation, encompasses administration of any inhibitor of this particular subunit of N-type calcium channel to treat depression. As fully explained in the previous office actions of record, voltage-gated calcium channels represent a major route of calcium transport across the plasma membrane of excitable cells. The art teaches that N-type channels are involved in release of major neurotransmitters such as norepinephrine, acetylcholine, adenosine and play direct role

in many diverse physiological functions (Fossier et al., 1994; Mynlieff et al., 1994 and Uneyama et al., 1999). The art does not recognize that N-type calcium channels, including 1B N-type calcium channels or subunits thereof are specifically associated with etiology or course of depression. Moreover, according to the knowledge in the art, depression represents a complex pathological mental condition, which is not limited to dysfunction of a single gene, see article by Blakely, 2005, Neuron, Vol. 48, pp. 701-2 (the article calls depression a complex endpoint condition which is result of contributions from many points in the network, bottom of column 2 at p. 701). The instant specification fails to present a single line of sound scientific reasoning to support a conclusion that the limited information/data provided at the time of filing are representative of and, therefore can be directly extrapolated to practicing the full scope of the claimed method, as currently presented by Applicant.

Moreover, Applicant is advised that claims 1 and 4 can be considered as single means claims because of the recitation of "an inhibitor of  $\alpha 1B$  subunit of N-type calcium channel". MPEP 2164.08(a) defines a single means claim as a claim which covered every conceivable means for achieving the stated purpose when the specification disclosed at most only those means known to the inventor. This type of claim was held to be nonenabling for the scope of the claim in *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983) because the specification disclosed at most only those means known to the inventor. When claims depend on a recited property (i.e. inhibition of  $\alpha 1B$  subunit of N-type calcium channel), a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the

inventor. This appears to be the instant case and the claims are not commensurate in scope with the specification.

For reasons of record fully explained earlier and reasons above, the instant rejection is maintained.

### ***Conclusion***

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Olga N. Chernyshev, Ph.D./

Primary Examiner, Art Unit 1649